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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,383	06/27/2005	Ulrik Darling Larsen	ALB.018	5689
20/987 7590 09/01/2010 VOLENTINE & WHITT PLLC ONE FREEDOM SQUARE 11951 FREEDOM DRIVE SUITE 1260 RESTON, VA 20190				
EXAMINER				
FRITCHMAN, REBECCA M				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
09/01/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/517,383

**Applicant(s)**

LARSEN ET AL.

**Examiner**

REBECCA FRITCHMAN

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06/22/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Detailed Action  
Summary***

This is the FINAL Office action based on the 10517383 application RCE attorney remarks filed 06/22/2010.

Claims 22-50 are pending and have been fully considered.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. **Claims 22-28, 33-37, & 39-50 are rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of SALDIVAR in US 5501982.**

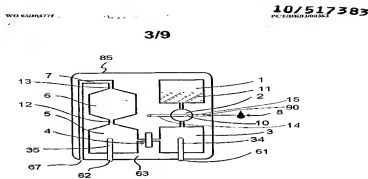
With respect to Claim 22, 49, & 50, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31) in one counting operation(column 3, lines 28-31, column 4, lines 13-14), comprising a housing with characterizing particles suspended in a liquid sample(liquid storage chamber)(column 3, lines 28-31, column 3, lines 39-48), connectors for operational connection to and disconnection from connectors of a docking station for establishment of electrical and fluid connections when the cartridge is received in the docking station(col. 4, l. 4-15; col. 6, l. 7-22) a first mixing

chamber(col. 4 l. 57-61), a first cell characterization means for characterizing cells passing through the first orifice(col. 4, l. 4-15), a bore in the outer surface of the housing for entrance of the blood sample(col 4, l. 24-33), communicating with a first sampling member positioned in the housing for sampling the blood sample and having a first cavity for receiving and holding the blood sample(col. 3, l. 49-55, figs 2-4), the member being movably positioned in relation to the housing in such a way that, in a first position, the first cavity is in communication with the bore for entrance of the blood sample into the first cavity(col. 3, l. 56-62), and in the second position, the first liquid storage chamber(col 3, l. 56-62, col. 4, l. 28-33) communicates through the first cavity with the first mixing member so that the blood sample can be flushed with discharged liquid from the first liquid storage chamber into the first mixing chamber(col. 3, l. 63-67; col. 4, l. 55-65), characterized in that the cartridge further comprises a first collection chamber separated by a wall from the first mixing chamber, the wall containing a first orifice for the passage of particles between the first mixing chamber and the first collection chamber(col. 5, l. 18-24), and in that the first particle characterization means is adapted for characterization of the particles passing through the first orifice(col. 5, l. 18-30).

Specifically, BERNDTSSON et al. teach of cylinder 61 in Figure 2 being the first liquid storage chamber, cylinder 44 being the first mixing chamber, capillary and blood recess 62 as the first collection chamber, electrodes 65 & 66 being the first cell characterization means, 55 as the bore, and valve(pressure source) 50 as the first sampling member BERNDTSSON et al. also teach of the first orifice being straddled by two electrodes(65 & 66)(the first half of the capillary channel is part of the mixing

chamber, while the last half is part of the collection chamber(column 4, lines 4-15). It appears from the instant application (Figure 3 below) requires a capillary or channel leading to and downstream from the orifice. BERNDTSSON et al. do not teach of a first liquid storage chamber holding a prestored lysing reagent with a lysing capability sufficient for lysing of erythrocytes while maintaining counting ability of other blood cell types.

SALDIVAR et al., however teach of another disposable cartridge for use with an analytical instrument for blood cell analysis, specifically one with a prestored lysing reagent capable of lysing erythrocytes while maintaining the countability of other blood cells types (col. 3, l. 27-30, fig 1., col. 7, l. 25-29, fig. 3 & 4). It would have been obvious to one of ordinary skill in the art to prestore a hemolysing reagent in the first liquid storage chamber of BERNSTSSON to allow for the reproducible counting of only white bloods cells(col. 3, l. 28-31) & due to the prior lack of ability to form reproducible results when counting white blood cells(col. 1, lines 40-56).



**Fig. 3**



**Fig. 4**

With respect to Claim 23 & 25, SALDIVAR et al. teach of the use of a surfactant(quatarnary ammonium salt)(col. 3, l. 27-30, & col 7., l. 25-29).

With respect to Claim 24, SALDIVAR et al. teach of the use of a surfactant(col. 3, l. 27-30, & col 7., l. 25-29). SALDIVAR does not teach of the use of saponin, however, saponin is an equivalent chemical for its use in the lysing agent as a surfactant.

With respect to Claims 26-28, SALDIVAR teaches of the use of isotonic solutions to be used with the lysing agent to minimize debris from red blood cells (col. 4, lines 52-63).

With respect to Claims 33, 34, & 47-48, it would be obvious to one of ordinary skill in the art from SALDIVAR that if red blood cells/lymphocytes are lysed they they will be reduced in size.

With respect to Claims 35 & 36, BERNDTSSON and SALDIVAR disclose the claimed invention except for the duplication of the mixing chamber, collection chamber, second orifice, second mixing chamber system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate these parts, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86, USPQ 70

With respect to Claim 37, BERNDTSSON teaches of housing with characterizing particles suspended in a liquid sample (reagent storage chamber) (column 3, lines 28-31, column 3, lines 39-48).

With respect to Claim 39, BERNDTSSON teaches of a mixing member being positioned in the mixing chamber (column 4, lines 66-67, & column 5, lines 1-17).

With respect to Claims 40 & 41, BERNDTSSON teaches of the use of a sensor for photometric measurement (column 6, lines 21-22).

With respect to Claims 42-46, BERNTSSON teaches of the hole for passage of blood cells having a diameter of 80 micrometers. It would be obvious to one of ordinary skill in the art to optimize the size of this diameter for the passage of cells.

2. **Claims 29-32 are rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of SALDIVAR in US 5501982 and in further view of MALLINCKRODT in EP 1182457(as cited on IDS dated 02/16/2005)**

With respect to Claim 29, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31) in one counting operation (column 3, lines 28-31, column 4, lines 13-14). SALDIVAR et al., however teach of another disposable cartridge for use with an analytical instrument for blood cell analysis, specifically one with a prestored lysing reagent capable of lysing erythrocytes while maintaining the countability of other blood cells types (col. 3, l. 27-30, fig 1., col. 7, l. 25-29, fig. 3 & 4). BERNDTSSON & SALDIVAR do not teach of the additional solution components to aid in specific analysis. MALLINKRODT teaches of the use of a urea compound in the diluent to be mixed with the lysing reagent (Claim 10). It would have been obvious to one of ordinary skill in the art to mix compounds such as these (urea & lysing agent) since they are known in the art to aid in specific analysis.

With respect to Claim 30, MALLINKRODT teaches of the use of cyanide for converting the product to a product suitable for spectrophotometric analysis (paragraph 0066).

With respect to Claim 31, MALLINKRODT teaches of the use of inorganic salts (paragraph 0055 7 0056).

With respect to Claim 32, MALLINKRODT teaches of the lysing reagent comprising hexadecyltrimethyl-ammoniumhalogenide (paragraph 0061).



3. **Claim 38 is rejected under 35 U.S.C. 103(a) as being obvious over BERNDTSSON in US 6387328 in view of SALDIVAR in US 5501982 and in further view of SEYMOUR in US 5393496.**

With respect to Claim 38, With respect to Claim 29, BERNDTSSON teaches of a cartridge for counting and discriminating a plurality of types of blood cells in a blood sample (column 1, lines 11-14, & column 3, lines 28-31) in one counting operation(column 3, lines 28-31, column 4, lines 13-14). SALDIVAR et al., however teach of another disposable cartridge for use with an analytical instrument for blood cell analysis, specifically one with a prestored lysing reagent capable of lysing erythrocytes while maintaining the countability of other blood cells types (col. 3, l. 27-30, fig 1., col. 7, l. 25-29, fig. 3 & 4). BERNDTSSON & SALDIVAR do not teach of a breakable seal separating the reagent chamber from the mixing chamber. SEYMOUR et al. do teach of a breakable seal in a sample testing device in which the seal breaks and allows the mixture of the buffering solution and the sample to flow. It would have been obvious to combine the breakable seal of SEYMOUR with BERNDTSSON and SALDIVAR due to prior teaching of sampling devices in which after the specimen is obtained, the specimen collector is forced through the seal into a liquid preservative(column 2, lines 10-15).

### ***Response to Arguments***

Applicant's arguments filed 06/22/2010 have been fully considered but they are not persuasive.

Applicant argues that the definition of a chamber is an enclosed space & therefore a channel would not read on this limitation. It is the examiner's understanding that a channel is an enclosed space (enclosed on two-3 sides) and therefore the BERNDTSSON patent is still applicable and used in the rejection.

Also, with respect to the applicant's arguments that " the sample does not reach bleed recess 62 in turning valve 50" with respect to the BERNDTSSON patent, the examiner disagrees. In the passage cited by the attorney (col. 5, lines 18-30, & Figure 8 & 9), it is no where stated that the sample does not reach the bleed recess. Therefore, the BERNSTSSON patent is still applicable.

Applicant's arguments with respect to claims 22-50 have been considered but are moot in view of the new ground(s) of rejection.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797

R.F.